



PATENT
Docket No.: 13024/38629A

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the Application of: McMichael, J.

Serial No.: 10/764,161

Filed: January 23, 2004

For: Method of Treatment of Conditions
by Administration of Streptolysin O

Group Art Unit: 1654

Examiner: To be assigned

) I hereby certify that this paper and the
documents referred to as enclosed
herewith are being deposited with the
United States Postal Service as First
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1450, on this date:
July 12, 2004


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Attorney for Applicant

**INFORMATION DISCLOSURE STATEMENT
PURSUANT TO 37 C.F.R. §§1.56 AND 1.97**

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

In compliance with 37 C.F.R. §1.97 and the duty of disclosure under 37 C.F.R. §1.56, the attached Form PTO/SB/08A is hereby submitted by the Applicant for consideration in connection with the above-identified patent application. Copies of documents C38-C42 are enclosed herewith. Copies of documents A1-A9, B1-B7 and C1-C37 have been previously submitted to the Patent Office in U.S. Serial No. 10/349,606, from which priority is claimed under 35 U.S.C. §120. However, copies of these documents will be resubmitted at the Examiner's request.

This Information Disclosure Statement is not intended to be an admission that a search has been made, that other relevant art does not exist, or that any of the information disclosed herein constitutes prior art under 35 U.S.C. §102 or §103.

This statement and the Form PTO/SB/08A are submitted before receipt of a first official action on the merits in the above-identified patent application. Accordingly, it is believed that no fee is due in this matter under 37 C.F.R. §1.97(b). However, if it is determined that any appropriate fee is due, please charge Deposit Account Number 13-2855. A duplicate of this paper is enclosed.

Respectfully submitted,

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July 12, 2004



PTO/SB/08A (10-01)

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Substitute for form 1449A/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				Application Number	10/764,161
Sheet	1	of	3	Filing Date	January 23, 2004
				First Named Inventor	John McMichael
				Art Unit	1654
				Examiner Name	To be assigned
				Attorney Docket Number	13024/38629A

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		Number-Kind Code ² (if known)		
A1	5,240,846		08-31-1993	Collins et al.
A2	5,292,498		03-08-1994	Boucher, Jr.
A3	5,420,116		05-30-1995	Puchelle et al.
A4	5,470,838		11-28-1995	von Borstel et al.
A5	5,576,289		11-19-1996	McMichael, J.
A6	5,726,160		03-10-1998	McMichael, J.
A7	5,736,508		04-07-1998	McMichael, J.
A8	5,948,768		09-07-1999	McMichael, J. et al.
A9	5,955,442		09-21-1999	McMichael, J.

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Country
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)		
B1	WO 92/11016		07/09/92	WIPO
B2	WO 93/12240		06/24/93	WIPO
B3	WO 94/23048		10/13/94	WIPO
B4	WO 95/25800		09/28/95	WIPO
B5	WO 96/32138		10/17/96	WIPO
B6	WO 96/40059		12/19/96	WIPO
B7	WO 97/05195		02/13/97	WIPO

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	C1	Alton, E.W.F.W. et al., "Noninvasive liposome-mediated gene delivery can correct the ion transport defect in cystic fibrosis mutant mice," <i>Chemical Abstracts</i> , 119:62 (1993) (ABSTRACT 217089w)	
	C2	Badesch et al., "Continuous Intravenous Epoprostenol for Pulmonary Hypertension Due to the Scleroderma Spectrum of Disease, A Randomized, Controlled Trial," <i>Ann. Intern. Med.</i> , 132:425-434 (2000).	
	C3	Baker, R.C., "Pitfalls in Diagnosing Acute Otitis Media," <i>Pediatric Annals</i> , 20:591-593, 596-598 (1991).	
	C4	Barst et al., "A Comparison of Continuous Intravenous Epoprostenol (Prostacyclin) With Conventional Therapy for Primary Pulmonary Hypertension," <i>N. Eng. J. Med.</i> , 334:296-301 (1996).	

Examiner Signature)	Date Considered
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449B/PTO				Complete if Known	
				Application Number	10/764,161
				Filing Date	January 23, 2004
				First Named Inventor	John McMichael
				Group Art Unit	1654
				Examiner Name	To be assigned
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C5	Berkow, R. (Ed.), <i>The Merck Manual of Diagnosis and Therapy</i> , Sixteenth Edition, Merck Research Laboratories, Division of Merck & Co., Inc., Rahway, N.J. pp. 600-602 (1992).
C6	Berman, S., "Otitis Media in Developing Countries," <i>Pediatrics</i> , 96:126-131(1995).
C7	Canonico, A.E. et al., "Expression Of A Cmv Promoter Driven Human A-1 Antitrypsin Gene In Cultured Lung Endothelial Cells And In The Lungs Of Rabbits," <i>Clin. Res.</i> , 39(2): 219A (1991).
C8	Carman et al., "A Primary Care Approach to the Patient with Claudication," <i>Am. Fam. Physician</i> , 61:1027-1032 (2000).
C9	Cunningham, M.W., "Pathogenesis of Group A Streptococcal Infections," <i>Clin. Microbiol.</i> 13:470-511 (2000).
C10	Dagan, R. et al., "Treatment Failures in Otitis Media-What Can We Learn?," <i>Ear, Nose and Throat J.</i> , 77:16-21(1998).
C11	Dawson et al., "Cilostazol Has Beneficial Effects in Treatment of Intermittent Claudication," <i>Circulation</i> , 98:678-686 (1998).
C12	DeGraves et al., "Economics of Mastitis and Mastitis Control," <i>The Veterinary Clinics of North America-Food Animal Practice Update on Bovine Mastitis</i> , 9:421-434 (1993).
C13	Flotte, T.R., et al., "Stable <i>in vivo</i> expression of the cystic fibrosis transmembrane conductance regulator with an adeno-associated virus vector," <i>Chemical Abstracts</i> , 120:229(1994) (ABSTRACT 46918e)
C14	furth et al., "Gene Transfer into Somatic Tissues by Jet Injection," <i>Analytical Biochemistry</i> , 205:365-368 (1992).
C15	Gent et al., "A Randomised, Blinded, Trial of Clopidogrel Versus Aspirin in Patients at Risk of Ischaemic Events (CAPRIE)," <i>Lancet</i> , 348:1329-1339 (1996).
C16	Gardner et al., "Exercise Rehabilitation Programs for the Treatment of Claudication Pain: A Meta Analysis," <i>JAMA</i> , 274:975-980 (1995).
C17	Goldhaber et al., "Low-Dose and Subsequent Peripheral Arterial Surgery in the Physicians' Health Study," <i>Lancet</i> , 340:143-145 (1992).
C18	Harrison et al., "Structural Features of Interstitial Lung Disease in Systemic Sclerosis," <i>Am. Rev. Respir. Dis.</i> , 144:706-713 (1991).
C19	Hood et al., "Management of Intermittent Claudication with Pentoxyfylline: Meta-Analysis of Randomized Controlled Trials," <i>CMAJ</i> , 155:1053-1059 (1996).
C20	Janzon et al., "Prevention of Myocardial Infarction and Stroke in Patients with Intermittent Claudication; Effects of Ticlopidine. Results from STMS, the Swedish Ticlopidine Multicentre Study," <i>J. Intern. Med.</i> , 27:301-308 (1990).
C21	Jarrow et al., "Peyronie's Disease and Radical Prostatectomy: Is There A Link?," <i>J. of Urology</i> , 158:1388-1390 (1997).
C22	Karver, S.B., "Otitis Media," <i>Ear, Nose and Throat Disorders</i> , 25:619-632(1998).
C23	Klein, J.O., "Otitis Media," <i>Clinical Infectious Disease</i> , 19:823-833 (1994).
C24	Ledley, F.D., "Non-viral gene therapy," <i>Current Opinion in Biotechnology</i> , 5: 626-636 (1994).
C25	Ledley, F.D., "Nonviral Gene Therapy: The Promise of Genes as Pharmaceutical Products," <i>Human Gene Therapy</i> , 6: 1129-1144 (September, 1995).
C26	Marshall, E., "Gene Therapy's Growing Pains," <i>Science</i> , 269: 1050-1055 (1995).

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	C27	Patterson et al., "Value of a Supervised Exercise Program for the Therapy of Arterial Claudication," <i>J. Vasc. Surg.</i> , 25:312-319 (1997).	
	C28	Razin et al., "Protein Kinases C- β and C- ϵ Link the Mast Cell High-Affinity Receptor for IgE to the Expression of c-fos and c-jun," <i>Proc. Natl. Acad. Sci. (USA)</i> , 91:7722-7726 (1994).	
	C29	Rosenfeld, M.A. et al., "Adenovirus-Mediated Transfer of a Recombinant α 1-Antitrypsin Gene to the Lung Epithelium in Vivo," <i>Science</i> , 252: 431-434(1991).	
	C30	Rosenfeld, J. et al., "Acute Otitis Media in Children," <i>Primary Care; Clinics in Office Practice</i> , 23(4):677-686(1996).	
	C31	Ruiz et al., "Streptolysin O and Adherence Synergistically Modulate Proinflammatory Responses of Keratinocytes to Group A Streptococci," <i>Mol. Microbiol.</i> 27:337-346 (1997).	
	C32	Schrager et al., "Hyaluronic Acid Capsule Modulates M Protein-Mediated Adherence and Acts as a Ligand for Attachment of Group A <i>Streptococcus</i> to CD44 on Human Keratinocytes," <i>J. Clin. Investig.</i> 101:1708-1716 (1998)	
	C33	Silver et al., "Evaluation and Management of Scleroderma Lung Disease Using Bronchoalveolar Lavage," <i>Am. J. Med.</i> , 88:470-476 (1990).	
	C34	Unemori et al., "Relaxin Modulates Synthesis and Secretion of Procollagenase and Collagen by Human Dermal Fibroblasts," <i>J. Biol. Chem.</i> , 265:10681-10685 (1990).	
	C35	Visa et al., "The Value of Fasciectomy in the Surgical Approach of the Dupuytren's Disease," <i>Romanian Journal of Hand and Reconstructive Microsurgery</i> , 5:9-13 (2000).	
	C36	Wallaert et al., "Subclinical Pulmonary Involvement in Collagen-Vascular Diseases Assessed by Bronchialveolar Lavage," <i>Am. Rev. Respir. Dis.</i> , 133:574-580 (1986).	
	C37	White et al., "Cyclophosphamide is Associated with Pulmonary Function and Survival Benefit in Patients with Scleroderma and Alveolitis," <i>Ann. Intern. Med.</i> , 132:947-954 (2000).	
	C38	Siebold et al., "Recombinant Human Relaxin in the Treatment of Scleroderma, A Randomized, Double-Blind, Placebo-Controlled Trial," <i>Ann. Intern. Med.</i> , 132:871-879 (2000).	
	C39	Murinda et al., "Isolation of Mastitis and Food-Borne Pathogens in Bulk Tank Milk and Fecal Samples from Cull Dairy Cows," Schrick et al., <i>Department of Animal Science Annual Report</i> , The University of Tennessee, Knoxville, in press.	
	C40	Taranta et al., "The Relationship of Sydenham's Chorea to Infection with Group A Streptococci," <i>Am. J. Med.</i> , 20:170-175 (1956).	
	C41	Kiessling et al., "Antineuronal Antibodies in Movement Disorders," <i>Pediatrics</i> , 92:39-43 (1993).	
	C42	Askanas et al., "A New Program for Investigating Adult Human Skeletal Muscle Grown Aneurally in Tissue Culture," <i>Neurology</i> , 25:58-67 (1975).	

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